Remarks

The Claim Amendments

Applicants have amended claims 9-16 to improve their form and correct their claim dependency. Support for added claims 21-30 may be found throughout the specification. Specifically, support for added claim 21 may be found on page 3, line 29 to page 4, line 3 and in originally-filed claim 2. Support for added claim 22 may be found in originally-filed claim 2. Support for added claim 23 may be found on page 10, lines 5-9 and page 2, lines 22-23. Support for added claim 24 may be found on page 10, lines 13-16. Support for added claim 25 may be found on page 10, lines 2-3. Support for added claims 26 and 27 may be found in originally-filed claims 7 and 8, respectively. Support for added claim 28 may be found on page 6, line 32, to page 7, line 1. Support for added claim 29 may be found on page 3, lines 6-8. Support for added claim 30 may be found on page 13, lines 25-26. No new matter is added by the amendments. Their entry is requested.

Applicants have canceled claims 1-8 and 17-20, amended claims 9-16, and added claims 21-30. Thus, claims 9-16 and 21-30 are pending. The Examiner has withdrawn claims 9-16 and 30 from consideration. Added claims 21-29 correspond to elected Group I and are subject to examination.

The Restriction Requirement and Request for Rejoinder

Applicants acknowledge that the Examiner has made the restriction requirement final. The Examiner states that the traversal of the restriction requirement is not persuasive because a search burden has been shown by the classification of the invention in different classes.

The Manual of Patent Examining Procedure (MPEP) §821.04 states that "if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined." Withdrawn claims 10-16 and added claim 30 are directed to processes of making or using the claimed product and include all the limitations

of the claimed product. Pursuant to MPEP §821.04, the Examiner should rejoin these claims to the elected claims upon allowance of the claims of Group I. In addition, claim 30 links the compound of claim 21 and the pharmaceutical composition of claim 9. Thus, pursuant to MPEP §809, claim 9 should be rejoined to the elected claims upon allowance of claim 30.

The Rejection Under 35 U.S.C. §102

The Examiner has rejected claims 1-2 and 4 under 35 U.S.C. §102(b) as being anticipated by WO 99/32134 (hereafter "the '134 application"). Specifically, the Examiner contends that the '134 application discloses mono-PEG-IL-10 conjugates with attachment to histidine. The Examiner also takes notice under MPEP § 2144.03 that the N-terminal amino acid of IL-10 is allegedly histidine. Applicants traverse.

Added claims 21-29 recite a pegylated IL-10 comprising one or more polyethylene glycol (PEG) molecules covalently attached via a linker to a single amino acid residue of IL-10, wherein the amino acid residue is the alpha amino group of the N-terminal amino acid residue of IL-10 or the epsilon amino group of a lysine residue. The '134 application does not disclose attachment to a single amino acid residue of IL-10. Although the '134 application discloses a mono-pegylated interferon alpha, interferon alpha comprises only a single polypeptide chain. In contrast, IL-10 is a non-covalently linked homodimer, and the '134 application does not teach or suggest how to conjugate a PEG molecule to a single amino acid of a homodimer. For this reason alone, the '134 application does not anticipate the claimed invention.

Further, the '134 application does not teach covalent attachment of PEG to the N-terminal amino acid or to a lysine residue of IL-10, but teaches only covalent attachment of PEG to IL-10 via a histidine residue. See, e.g., page 28, line 26 to page 29, line 9. Although the Examiner asserts that the N-terminal amino acid of IL-10 is histidine, applicants know of no species of IL-10 that has an N-terminal histidine. Indeed, the N-terminal amino acid residue of immature IL-10 from all species is likely to be methionine, as it is well known in the art that virtually all polypeptides are initially synthesized with an N-terminal

methionine. Further, the N-terminal amino acid residue of mature human and mouse IL-10 is serine. See, e.g., Viera et al., *Proc. Natl. Acad. Sci. USA* 88: 1172-76 (1991), page 1173 and Figure 1 (enclosed herewith as Exhibit A). Thus, the '134 application does not anticipate or render obvious the claimed invention because it does not teach or suggest the covalent attachment of PEG to the N-terminal amino acid or to a lysine residue of IL-10.

Conclusion

Applicants request that the Examiner allow the pending claims and pass this application to issue.

If the Examiner should have any questions regarding this response or application, he is encouraged to contact the undersigned agent.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

September 24, 2003
Date of Deposit

KAREN E. BROWN
Registered Representative

Karen E. Brown
Signature

9/24/03
Date of Signature